

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GRA3189PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/014147	International filing date (<i>day/month/year</i>) 13.12.2004	Priority date (<i>day/month/year</i>) 12.12.2003
International Patent Classification (IPC) or national classification and IPC C08J5/18, C08J3/24, A61 K9/00, A61 K9/70, C08B15/00		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-21 as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-9 received by this Authority on 06.12.2005 with letter of 02.12.2005
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims 1-4	YES
		Claims 5-9	NO
	Inventive step (IS)	Claims	YES
		Claims 1-9	NO
	Industrial applicability (IA)	Claims 1-9	YES
		Claims	NO
2.	Citations and explanations (Rule 70.7)		
	This report makes reference to the following documents:		
	<p>D1: US-B1-6 375 963 (REPKA MICHAEL A ET AL) 23 April 2002 (2002-04-23)</p> <p>D2: WO 99/55312 A (VIROTEX CORPORATION) 4 November 1999 (1999-11-04)</p> <p>D3: WO 98/22097 A (BIO ADVANCES1 LLC) 28 May 1998 (1998-05-28)</p> <p>D4: WO 01/58430 A (NATIONAL STARCH AND CHEMICAL INVESTMENT HOLDING CORPORATION) 16 August 2001 (2001-08-16)</p> <p>D5: EP-A-0 410 696 (E. R. SQUIBB & SONS, INC) 30 January 1991 (1991-01-30)</p> <p>D6: WO 03/063839 A (NATIONAL STEEL CORPORATION; UNIVERSITEIT UTRECHT; NATIONAL STARCH AND) 7 August 2003 (2003-08-07)</p> <p>D7: DE10146251 A1 (2003-04-17), cited in the application</p>		
	<p>1. The subject matter of claims 5 to 9 of the application is not novel (PCT Article 33(2)) in light of the optionally multilayered film-forming administration forms disclosed in D1 to D6, said administration forms</p>		

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

having an active substance-containing layer of a polyacrylic acid derivative and a polysaccharide, such as hydroxypropyl(methyl)cellulose or hydroxyethylcellulose, wherein, in the production thereof, naturally an at least partial crosslinking between the polyacrylic acid derivative and the polysaccharide took place (see the text passages cited in the search report). It should also be noted that a product is not automatically novel just because it has been produced by means of another method.

2. The subject matter of claims 1 to 4 is obvious (PCT Article 33(3)) from the routine use of known devices (see D7, figure 4 and claim 10), wherein a two-substance nozzle, which permits different solutions of polymers and crosslinkers to be sprayed simultaneously, is used in the production of optionally multilayered film-forming administration forms by means of spraying, as disclosed in D2, D3 or D4. It should also be noted that such a device is used for the only comparative test of the application, and the problem addressed by the application can therefore only be that of providing other good methods of producing film-forming administration forms. The application does not contain anything that could substantiate a more ambitious problem to be solved (for example, providing an improved method of producing a film-forming administration form) in relation to the searched prior art.